

PATENT

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Signature

Applicant	:	Claudio P. Plaza	Confirmation No. 7287
Application No.	:	10/820,480	
Filed	:	April 2, 2004	
Title	:	IRRIGATED CATHETER HAVING A POROUS TIP ELECTRODE	
Grp./Div.	:	3739	
Examiner	:	Michael F. Peffley	
Docket No.	:	51991/W112	

APPELLANT'S REPLY BRIEF

Mail Stop Appeal Brief-Patents
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Commissioner:

In his Examiner's Answer, the Examiner argues that Skalsky is relied on "merely as a teaching of the known methods of making a porous electrode," and that "[t]he function of the electrode is immaterial to the rejection." Examiner's Answer, page 5. However, as noted in Appellant's Brief, obviousness requires a reasonable expectation of success, which in turn, requires that "one skilled in the art could have combined the elements as claimed by known methods with no change in their respective *functions*." MPEP §2143.02. As a determination of the existence of a reasonable expectation of success requires an evaluation of the respective *functions* of the combined elements, the function of the electrode is indeed material to the obviousness rejection. In particular, to support an obviousness rejection, the electrode from Skalsky that the Examiner asserts may be combined with the catheter of Moaddeb must be combinable by known methods *with no change in its function*. As discussed in Appellant's brief,

the combination suggested by the Examiner does not satisfy these requirements. Quite to the contrary, the combination suggested by the Examiner would lead to a significant change in the function of the Skalsky electrode. As admitted by the Examiner in his Answer, the Skalsky device is a pacing lead, and the disclosed electrode is designed to promote tissue ingrowth. *See* Examiner's Answer, page 6. Indeed, the Skalsky pacing lead is implanted and left in the heart for a prolonged period of time, and the function of the porous member in Skalsky is to promote tissue ingrowth to facilitate secure placement of the electrode in the heart. Skalsky, column 7, lines 1-14.

In significant contrast, the catheter disclosed in Moaddeb is designed for temporary use during a mapping and/or ablation procedure. As is known in the art, mapping and/or ablation procedures, while relatively short, can last several hours. Given that any electrode used in the Moaddeb device would be in the body for several hours, and given the disclosure in Skalsky that the disclosed electrode configuration promotes tissue ingrowth when used in connection with a pacing lead, those of ordinary skill in the art would expect that the same or similar electrode configuration would also promote tissue ingrowth when used in connection with a catheter that remains in the body for several hours. Accordingly, combining the elements of Skalsky with those of Moaddeb in the manner suggested by the Examiner would destroy the function of the Moaddeb catheter (i.e., to map or ablate within the heart over a period of several hours and then be removed from the body). However, in response to the Examiner's argument that "there would be no expectation of tissue ingrowth because the Moaddeb device is not left in place as is the Skalsky lead" (which Applicant refutes), such a result would destroy the function of the Skalsky electrode (i.e., to promote tissue ingrowth to place the electrode in the heart). As Skalsky and Moaddeb cannot be combined in the manner suggested by the Examiner with *no change in the respective functions of the combined elements*, the present claims are not obvious over those references.

The Examiner also argues that "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference," but rather "the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." Examiner's Answer, pages 5-6 (citing *In re Keller*, 208 USPQ 871

(CCPA 1981)). However, MPEP §2145(III), which discusses the *In re Keller* case, also states that the combination "cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose." Here, combining Skalsky and Moaddeb as suggested by the Examiner render Moaddeb inoperable for its intended purpose. In particular, as discussed above, Moaddeb is directed to a catheter used to ablate and/or map regions within the heart. Such procedures, while temporary, can last several hours, and may involve moving the device from location to location. Those of ordinary skill in the art would recognize the several hours of the procedure as a sufficient amount of time for the Skalsky electrode to affix itself to tissue through its tissue ingrowth function. As the affixation of the electrode would prevent, or at least make very difficult and risky the movement of the Moaddeb catheter from location to location, the affixation of the electrode to tissue during the mapping and/or ablation procedure would render the Moaddeb device inoperable for its intended purpose. Accordingly, the combination of Skalsky and Moaddeb does not render the present claims obvious.

Turning to Truckai, the Examiner argues that "[w]hile Skalsky is interested in promoting tissue ingrowth and therefore uses a thick coating,...[I]t is of ordinary skill in the art would recognize that electrodes of *different functions* (e.g. ablation or coagulation) would provide the coating in a manner appropriate for the electrode function." However, as discussed above, obviousness requires that "one skilled in the art could have combined the elements as claimed by known methods with no change in their respective *functions*." Here, the Examiner apparently admits that combining Skalsky with Truckai and Moaddeb would result in a *different function* of the Skalsky electrode. As combining Skalsky with Truckai and Moaddeb would alter the function of the combined elements, the combination of those references does not render the present claims obvious.

Moreover, a reference relied on as a basis for an obviousness rejection "must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 U.S.P.Q. 2d 1443, 1445 (Fed. Cir. 1992) (reciting the analogous art test); *see also* MPEP § 2141.01(a). Here, Skalsky is not in the field of applicant's endeavor, as Skalsky is directed to a pacing lead designed to be implanted and left in the heart, while the present claims relate to a catheter used to

ablate and/or map a region of the heart during a relatively short procedure and which is removed from the heart. Indeed, the Patent Office recognizes that Skalsky and the present application are related to different fields of endeavor, as the classifications for Skalsky and the present application are completely different (i.e., Skalsky - 128/875; 128/786; 128/419; present application - 606/041). Although the different classifications are not dispositive, they are strong evidence that Skalsky is not in Applicant's field of endeavor. In addition, one having ordinary skill in the art to which the present application pertains would not look to the implantable pacing leads of Skalsky for ideas on modifying the removable catheters for temporary use of the present application. *See, e.g., Wang Laboratories Inc. v. Toshiba Corp*, 26 U.S.P.Q. 2d 1767, 1773 (Fed. Cir. 1993) (*reh'g denied*) (holding that a patent directed to large, easily replaceable memory modules for *industrial* computers was outside the field of endeavor of an application directed to compact memory modules for *personal* computers). Like in *Wang*, the implantable pacing leads of Skalsky are not in Applicant's field of endeavor as defined by the present claims, which are directed to irrigated electrode catheters.

A reference that is not in Applicant's field of endeavor may nonetheless be analogous if the reference logically would have commended itself to the attention of a person having ordinary skill in the art trying to solve the problems addressed by the Applicant. Here, however, Skalsky does not relate to the particular problem addressed by the present application and claims. As explained in Skalsky, the purpose of the porous electrode is to promote tissue ingrowth in order to place the lead in the heart. Skalsky, column 2, line 54 to column 3, line 8. In significant contrast, the catheters described in the present specification are irrigated electrode catheters having porous electrodes with increased structural integrity that produce a reduced coolant flow by utilizing the coolant as efficiently as possible. *See* specification, page 3, line 15 to page 4, line 9. As such, the problems addressed by Skalsky and those addressed by the present application and claims are completely unrelated. *See, e.g., Wang Laboratories Inc. v. Toshiba Corp*, 26 U.S.P.Q. 2d 1767, 1773 (Fed. Cir. 1993) (*reh'g denied*) (holding that a patent directed to a memory circuit for a larger, more costly industrial controller would *not* have commended itself to the attention of a person having ordinary skill in the art attempting to provide compact personal computer memory with minimum size, low cost, easy reparability and easy

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expandability). As in *Wang*, Skalsky (directed to the affixation of a pacing lead electrode to heart tissue by promoting tissue ingrowth) would not have logically commended itself to the attention of a person having ordinary skill in the catheter art trying to solve the problems addressed by Applicant (i.e., increasing the structural integrity of, and improving the coolant flow through a porous electrode).

As Skalsky is neither in the field of Applicant's endeavor nor pertinent to the particular problem addressed by Applicant, Skalsky is directed to non-analogous art. Accordingly, Applicant respectfully submits that the obviousness rejection is improper.

Respectfully submitted,

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